K103288

510(K) Summary

JAN 3 1 2011

Submitter:	El.En. S.p.A. via Baldanzese, 17 50041 Calenzano (FI), Italy
Contact:	Paolo Peruzzi Senior Regulatory Affairs Engineer & Official Correspondent Phone: +39.055.8826807 E-mail: standards@elen.it
Date Summary Prepared:	January 28, 2010
Device Trade Name:	Deka Synchro FT
Common Name:	Medical laser and pulsed light system
Classification Name:	Laser Surgical Instrument for use in General and Plastic Surgery and in Dermatology (21 CFR 878.4810)
Equivalent Devices:	El.En. Synchro HP Platform (K082039), El.En. Minisilk FT (K082040)
Device Description:	The Deka Synchro FT is a platform which can be equipped with an internal hi-power long pulse Nd:YAG laser module and a pulsed light handpiece (FT handpiece). SynchroFT with the long pulse Nd:YAG module comes with a wide range of interchangeable, quick release handpieces with electronic spot recognition. The FT handpiece is equipped with five different emission spectra interchangeable filters. The system allows to switch from one of the two available sources to the other by pressing a key on keyboard. Handpiece activation is either by footswitch or fingerswitch. Overall weight of the device is 65 kg, and the size is 100 cm x 50 cm x 83 cm (H x W x D). Electrical requirement is 230VAC, 16A, 50-60 Hz, single phase.
Intended Use:	The Deka Synchro FT is indicated for the following treatments: Nd:YAG laser: Removal of unwanted hair, for stable long term or permanent hair reduction (Skin Types Fitzpatrick I-VI), photocoagulation and hemostasis of pigmented and vascular lesions, such as but not limited to warts, teleangiectasia, leg veins and spider veins, treatment of benign pigmented lesions.. Pulsed light attachment: Permanent hair reduction, photocoagulation of vascular lesions, photothermolysis of blood vessels, treatment of benign pigmented lesions.

Different wavelength ranges of Pulsed Light attachment are indicated for the various treatments and skin types, as indicated in the following table:

Pulsed light wavelength range	Hair reduction	Vascular lesions	Blood vessels	Pigmented lesions
500 - 1200nm	-	Skin Types I, II	Skin Types I, II	-
520 - 1200nm	-	Skin Type III	Skin Type III	Skin Types I, II
550 - 1200nm	Skin Types I, II	-	-	Skin Type III
600 - 1200nm	Skin Type III	-	-	-
650 - 1200nm	Skin Type IV	-	-	Skin Type IV

Comparison: The Deka Synchro FT is substantially equivalent to the El.En. Synchro HP Platform as regards the Nd:YAG laser and to the El.En. Minisilk FT as regards the Pulsed light attachment. The Deka Synchro FT has the same indications for use as the abovementioned predicate devices, with same principle of operation and essentially the same performances.

Nonclinical Performance Data: None

Clinical Performance Data: None

Conclusion: The Deka Synchro FT is a safe and effective device for the indications specified above.

Additional Information: None

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

El.En. S.p.A.
% Mr. Paolo Peruzzi
Senior Regulatory Affairs Engineer
via Baldanzese, 17
50041 Calenzano (FI), Italy

JAN 3 1 2011

Re: K103288
Trade/Device Name: Deka Synchro FT
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX, ONF
Dated: January 18, 2011
Received: January 20, 2011

Dear Mr. Peruzzi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(K) Number (if known): K103288

Device Name: Deka Synchro FT

Indications For Use:

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Nd:YAG laser: Removal of unwanted hair, for stable long term or permanent hair reduction (Skin Types Fitzpatrick I-VI), photocoagulation and hemostasis of pigmented and vascular lesions, such as but not limited to warts, teleangiectasia, leg veins and spider veins, treatment of benign pigmented lesions.

Pulsed light attachment: Permanent hair reduction, photocoagulation of vascular lesions, photothermolysis of blood vessels, treatment of benign pigmented lesions.

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550 - 1200nm	Skin Types I, II	-	-	Skin Type III
600 - 1200nm	Skin Type III	-	-	-
650 - 1200nm	Skin Type IV	-	-	Skin Type IV

Prescriptive Use ✓ OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE NO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K 103288

(Optional Format 1-2-96)